

ATTACHMENT A: MEDICATION GUIDE

Medication Guide

KRYSTEXXA™ (Phonetic spelling: Kris-TEX-a)

(pegloticase) Injection

For Intravenous Infusion

Read this Medication Guide before you start receiving KRYSTEXXA and before each treatment. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. Talk to your doctor if you have any questions about your treatment with KRYSTEXXA.

What is the most important information I should know about KRYSTEXXA?

Serious allergic reactions may happen in some people who receive KRYSTEXXA. These allergic reactions can be life threatening and usually happen within 2 hours of the infusion.

KRYSTEXXA should be given to you by a doctor or nurse in a healthcare setting where serious allergic reactions can be treated. Your doctor or nurse should watch you for any signs of a serious allergic reaction during and after your treatment with KRYSTEXXA.

Tell your doctor or nurse right away if you have any of these symptoms during or after your treatment with KRYSTEXXA:

- wheezing, shortness of breath, cough, chest tightness, chest pain, or trouble breathing
- dizziness, fainting, fast or weak heartbeat or feeling nervous
- reddening of the face, itching, hives, or feeling warm
- swelling of the throat or tongue, throat tightness, hoarse voice or trouble swallowing

What is KRYSTEXXA?

KRYSTEXXA is a prescription medicine used in adults to help reduce the signs and symptoms of gout that are not controlled by other treatments.

People with gout have too much uric acid in their body. Uric acid crystals collect in joints, kidneys, and other organs. This may cause pain, redness and swelling (inflammation). KRYSTEXXA works to lower blood levels of uric acid.

It is not known if KRYSTEXXA is safe and effective in children.

Who should not receive KRYSTEXXA?

Do not receive KRYSTEXXA if you have a rare blood problem called glucose 6-phosphate dehydrogenase (G6PD) deficiency or favism. Your doctor may test you for G6PD before you start KRYSTEXXA.

What should I tell my doctor before receiving treatment with KRYSTEXXA?

Before you receive KRYSTEXXA, tell your doctor if you:

- know you have G6PD deficiency
- ever had any heart problems or high blood pressure
- are pregnant or plan to become pregnant. It is not known if KRYSTEXXA will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if KRYSTEXXA passes into your breast milk. You and your doctor should decide if you will receive KRYSTEXXA or breastfeed.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines and show them to your doctor and pharmacist when you get a new medicine.

How will I receive KRYSTEXXA?

- **Your doctor may give you medicine before your treatment of KRYSTEXXA to help reduce your chance of getting a reaction. Take these medicines as directed by your doctor or nurse.**
- You will receive KRYSTEXXA through a needle in your vein (i.v. infusion).
- Your treatment will take about 2 hours or sometimes longer. A doctor or nurse will give you the treatment.
- You will receive KRYSTEXXA every 2 weeks.
- If you have side effects, your doctor may stop or slow the infusion and may give you medicine to help the side effects.
- A doctor or nurse will watch you for side effects while you receive KRYSTEXXA and for some time afterwards.
- Your doctor may stop your KRYSTEXXA if your uric acid levels do not become normal and stay controlled or you have certain side effects.
- Your gout flares may increase in the first 3 months when you start receiving KRYSTEXXA. Do not stop receiving KRYSTEXXA even if you have a flare as the amount of flares will decrease after 3 months of treatment. Your doctor may give you other medicines to help reduce your gout flares for the first few months after starting KRYSTEXXA.

What are the possible side effects of KRYSTEXXA?

KRYSTEXXA may cause serious side effects. See “What is the most important information I should know about KRYSTEXXA.”

The most common side effects of KRYSTEXXA include:

- gout flares
- allergic reactions. See “What is the most important information I should know about KRYSTEXXA.”
- bruising
- sore throat
- constipation
- chest pain
- vomiting

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the side effects of KRYSTEXXA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Savient Pharmaceuticals at 1-888-579-7839.

General information about the safe and effective use of KRYSTEXXA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about KRYSTEXXA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about KRYSTEXXA that is written for health professionals.

For more information, go to www.KRYSTEXXA.com or www.SAVIENT.com or call 1-888-579-7839.

What are the ingredients in KRYSTEXXA?

Active ingredient: pegloticase

Inactive ingredients: disodium hydrogen phosphate dihydrate, sodium chloride, sodium dihydrogen phosphate dihydrate, and water for injection.

Product manufactured for:

Savient Pharmaceuticals, Inc.
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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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